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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/640,211	08/16/2000	Marion Wood	11000.1021clu	3582
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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/25/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/640,211

Applicant(s)
Wood et al.

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 12, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 5-29, and 31-35 is/are pending in the application.
- 4a) Of the above, claim(s) 7 and 17-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 5, 6, 8-16, and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 2, 5-29, and 31-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 and 6 6) ☐ Other:

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Response to Amendment

1. The amendment filed 2/12/2003 has been entered. Following the entry of the amendment, claims 2, 5-29 and 31-35 are pending. Claims 7 and 17-29 are non-elected group which are withdrawn from further consideration.
3. The objection of the specification and claim 33 are withdrawn.
4. The rejection of claim 33 under 35 U.S.C. §112 second paragraph is withdrawn.
5. The international search report and GenBank data as listed in the PTO-1449 filed 12/26/2000 have been considered based upon the response filed 2/12/2003. The PTO-1449 is provided with this Office action.
6. The rejections of claims 31 and 33 under 35 U.S.C. §102(b) as being anticipated by Uimari et al. is withdrawn.
7. Claims 2, 5, 6, 8-16 and 31-34 remain rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the isolated polynucleotides consisting of SEQ ID. NO: 2076. It would require undue experimentation to make and use the claimed oligonucleotide. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The response argue that the instant specification clearly teaches methods for determining the percentage of identity of two sequences (see pg. 18, lines 13 - pg. 20 line 12), together with the preparation of DNA constructs comprising the inventive polynucleotides (See pg. 23, line 25 to pg 29, line 4) using the DNA constructs to modify gene expression in plants.

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The response also argue that Myb transcription factor contain DNA-binding domains has a high level of conservation in the art evidenced by Martin and Pas-Ares (Trends Genet., 1997, 13: 67-73 and Reichmann et al. (Science, 2000, 290: 2105-2110).

However, the claims recites that an oligonucleotide probe or primer comprises at least 20 contiguous residues complementary to 20 contiguous residues of SEQ ID NO: 2076 and other limitations recited in claims 32-34. These limitations are read on the entire chromosome and the specification does not teach to prepare chromosome DNA which comprises at least 20 contiguous residues complementary to 20 contiguous residues of SEQ ID NO: 2076 and the isolated polynucleotide which has the feature as recited in claims 31-34. Thus, the rejection is maintained.

7. Claims 2, 32, and 34 remain rejected under 35 U.S.C. §102(b) as being anticipated by Uimari et al..

As to claim 2, based upon the nucleic acid search report, the DNA sequence encoding Myb protein disclosed by Uimari et al. comprises that an oligonucleotide probe or primer comprises at least 20 contiguous residues complementary to 20 contiguous residues of SEQ ID NO: 2076 (See the attached nucleic acid search report).

As to claims 32, the response argues that the comparison between SEQ ID NO: 2076 and the sequence of Uimari et al. is with part of SEQ ID NO: 2076. However, the claim language does not limit to the full length sequence of SEQ ID NO: 2076.

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The Declaration of Dr. Elizabeth Visser filed herewith is considered, but it is not persuasive because the claim language does not limit to the full length sequence of SEQ ID NO: 2076.

As to claim 34, based upon the nucleic acid search report, the DNA sequence encoding Myb protein disclosed by Uimari et al. comprises that a sequence selected from the group consisting of nucleotide sequences that are 20 mer of SEQ ID NO: 2076 (See the attached nucleic acid search report).

Thus, the teachings of Uimari et al. anticipate the limitations of claims 2, 32 and 34.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

8. Claim 35 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide consisting of SEQ ID NO: 2076 encoding SEQ ID NO: 2249, does not reasonably provide enablement for an isolated polynucleotide sequence beyond the sequence disclosed as SEQ ID NO: 2076 encodes SEQ ID NO: 2249. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with the claim. .

In Ex parte Forman, 230 USPQ 546 (Bd. App. 1986) the board considered the issue of enablement in molecular biology. The Board summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the

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invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance presented as regards the sequence of oligonucleotides claimed beyond the sequences disclosed as SEQ ID. No 2076 which encodes SEQ ID NO: 2249. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability as to which sequences can be added to the oligonucleotide, and said oligonucleotide remain functional. The addition of sequences may allow for nonspecific interactions which would invalidate any assay, cause the formation of stem loops or other undesirable secondary structure, or interfere with hybridization to the template. Without providing the sequence for which protection is desired an infinite number of nucleotide sequences will have to be prepared and tested before they can be used in experiments.

As regards the nature of the invention, the claimed invention is drawn to an isolated polynucleotides. Polynucleotides are chemical compounds with an exact nucleotide sequence and claims drawn to the isolated polynucleotides should clearly define the nucleotide sequence for which protection is desired. While the breadth of these claims includes any oligonucleotide which includes the specified SEQ ID NO within its sequence, the specification lacks guidance on what additional sequences are to be added to the stated oligo.

The specification does provides a working example to make polynucleotide SEQ ID NO: 2076 which encodes SEQ ID NO: 2249 (See pg. 34-36, example 1). However, there is no working example provided to make an isolated polynucleotide sequence beyond SEQ ID NO: 2076 which encodes SEQ ID NO: 2249. Accordingly, undue experimentation is required to make and use the invention as claimed.

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See M.P.E.P. §§ 706.03(n) and 706.03(z).

8. No claims are allowable.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

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Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

JT

April 9, 2003



Ethan Whisenant, Ph.D.
Primary Examiner
Art Unit 1634